

PraxisAuril response to the AMRC proposals for changes to IP Guidance.

The Association of Medical Research Charities (AMRC) is consulting on revisions to its IP guidance, first developed in 1997. The new guidance has been developed with the aim of simplifying policies and practices relating to IP and its commercialisation.

“This is in order to encourage those they fund to engage with translation and in particular to minimise the administrative burden on institutions or TTOs.”

The proposed guidance is of direct relevance to PraxisAuril members, who work in research / enterprise and technology transfer offices. We would, therefore, have liked to see the inclusion of a KE practitioner in the AMRC consultation group to comment on the proposal as it was developed. Too often we see decisions about commercialisation policy and practice made without the informed opinion of expert practitioners.

We acknowledge the important role that AMRC members have in the research and innovation ecosystem and the significant impact of charity-funded research. Research and subsequent commercialisation activities require significant investment, which is worth it to achieve impact goals.

Common goals and managing risk

PraxisAuril members work to make research have impact in many different ways, including through commercialisation of IP. This ‘public good’ goal is common to both Medical Charities and universities (which are also charities) in this case, using research for public benefit to get new medicines and therapies to patients as quickly as possible.

Charitable organisations also share a concern for public benefit and for their own reputations as research funders and agents. Universities have invested significant funds over a long period of time to develop the infrastructure and expertise to carry out research. Research projects often have many funders and there is always significant investment by the university themselves, either in carrying out historic research or in making up for the shortfall in the funding provided by others.

Identifying, protecting and commercialising IP requires experienced and skilled staff and universities have invested in this resource over a long time. Technology Transfer staff have a ‘whole picture’ point of view of any single research outcome and understand how to treat projects with multiple funders, how to identify background IP, and how to present options for exploitation to researchers, funders and potential investors. Having concern for investment further down the line is an important consideration even at an early stage of commercialisation discussions.

Charities do not contribute to indirect costs and, for some of our members, this means paying not much more than half of the real costs of conducting research. Although the government uplift in CRSF is welcome, this contribution does not make up the shortfall and universities top up the remaining costs (potentially over 25%) themselves. This must be acknowledged in any revenue sharing proposals. Dedicated institutional resources for commercialisation have also been built up over time, and universities expend resources on every project – a risk that is borne by them and not the funders. Academics benefit from dedicated support that is not predicated on the financial success of an individual project. Most universities have placed a strong emphasis on ensuring that technology transfer is not driven by profit, but by impact, meaning that they deliberately take on

projects where impact is high, but revenues are low. We hope that the AMRC and its members would also acknowledge that generating income is not the only consideration for research project outcomes.

The proposal as it stands would result in funders taking an inequitably large return from a process in which they only contribute to costs, and do not take any risks in investing in translation.

Complexity

One of our concerns is that these proposals could actually result in more complexity for technology transfer.

There has been a great deal of criticism about the time it takes for research to reach beneficiaries, perhaps in the form of a new drug or treatment, and this criticism has often been aimed at technology transfer processes. The AMRC proposals recommend greater involvement of funders to grant consent to, for example, commercial exploitation of IP developed in the course of a grant. However, increasing the number of parties that need to grant consent at any stage of the process slows it down, meaning that impact could take longer to reach patients. If those who need to give consent do not have the expertise to give it, extra time and costs would be incurred seeking advice. Building up trust and enabling one, experienced party to lead and make decisions on technology transfer (as universities routinely do between themselves) is essential to a speedy resolution.

We do also understand the importance of good stakeholder communication in technology transfer and that this is vital to building trust. This extends to giving assurance to funders that processes and standards are in place for the treatment of research grants and their outcomes, and that these meet expectations for such. To avoid creating additional hurdles for IP exploitation, PraxisAuril and the AMRC could work with our respective members to understand where process seems unclear and what kind of assurances are needed to give funders confidence that grant recipients are also working to achieve the best possible outcomes for patient impact.

Income

The consultation states that *“medical research charities...must necessarily fundraise and...view revenue sharing activity as a source of potential funding”*.

In the Dowling review (2015) universities were criticised for taking a short-term, revenue focused approach to commercialisation. The AMRC’s proposals put a great deal of emphasis on revenue without acknowledging the long timescales involved in medical research commercialisation, the investment required by universities (from many sources), the risks of that investment, and the low prospects of return on investment (even if impact is high).

Technology transfer is expensive and most projects make little or no money (which is not to say that they do not have high impact). It is important that revenues are ploughed back to cover the cost of technology transfer, so that all projects can receive the support they need. Universities have publicly available IP policies which include revenue sharing policies designed to make returns to the institution and the individual; these policies are the result of strategic decisions designed to incentivising academic researchers and adequately reward them for their commitment to the shared goal of successful translation.

Academics will normally be funded from the university's share unless they have opted out of a revenue share scheme by taking a shareholding in the spin out company or are being reimbursed through another route. It cannot be assumed that universities will always fund academics out of their share.

The wider context

The AMRC's consultation closes in the same week that the House of Lords Science & Technology Select Committee report on the Life Sciences Sector and the Industrial Strategy "[Who's driving the bus?](#)". The inquiry report points (among other things) to the complexity of implementing the Industrial Strategy and the many aspects of funding and infrastructure that are necessary to create the right collaborative environment to achieve the government's 2.4% R&D target.

To create the right funding and investment environment for creating and sustaining world-class medical research, universities and funders need to work together to:

- Underline common goals to achieve impact through IP and non-IP based KE
- Acknowledge the different skills and contributions of funders and their research partners to research projects and their outcomes
- Design appropriate grant reporting structures that do not create additional burden but recognise the contribution of all funders to monetary and non-monetary outcomes
- Increase understanding of the conditions for successful IP-based research translation in the long-term.

In making this submission, PraxisAuril acknowledges the expert input of members and also their contributions to individual institutional and mission group representations on this matter. We have also referred to the statement by our sister organisation, AUTM, which addresses the relationship between universities and Foundations in the US and makes many similar points about trust, risk management and revenue sharing:

<https://www.autm.net/AUTMMain/media/Advocacy/Documents/Foundation-3-Points-to-Consider-5-15-15.pdf>

Please do not hesitate to contact us if you would like to discuss any item in this response.

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PraxisAuril

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